

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB
Display Date 9.26.02
Publication Date 9.27.02
Certifier G. Penley

Food and Drug Administration

Biological Response Modifiers Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Biological Response Modifiers Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held by teleconference on October 10, 2002, 5:30 p.m. to approximately 7:30 p.m.

Location: National Institutes of Health, Bldg. 29B, conference room C, 29 Lincoln Dr., Bethesda, MD. This meeting will be held by a telephone conference call. Members of the public attending the meeting may participate during the open session of the meeting.

Contact Person: Gail Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

oc02234

3897

NM1

Agenda: On October 10, 2002, the committee will receive an update on individual research programs in the Division of Cell and Gene Therapies and the Division of Therapeutic Proteins.

Procedure: On October 10, 2002, from 5:30 p.m. to approximately 7 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 3, 2002. Oral presentations from the public will be scheduled between approximately 6 p.m. and 7 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 3, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On October 10, 2002, from approximately 7 p.m. to 7:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of a review of individual research programs in the Center for Biologics Evaluation and Research.

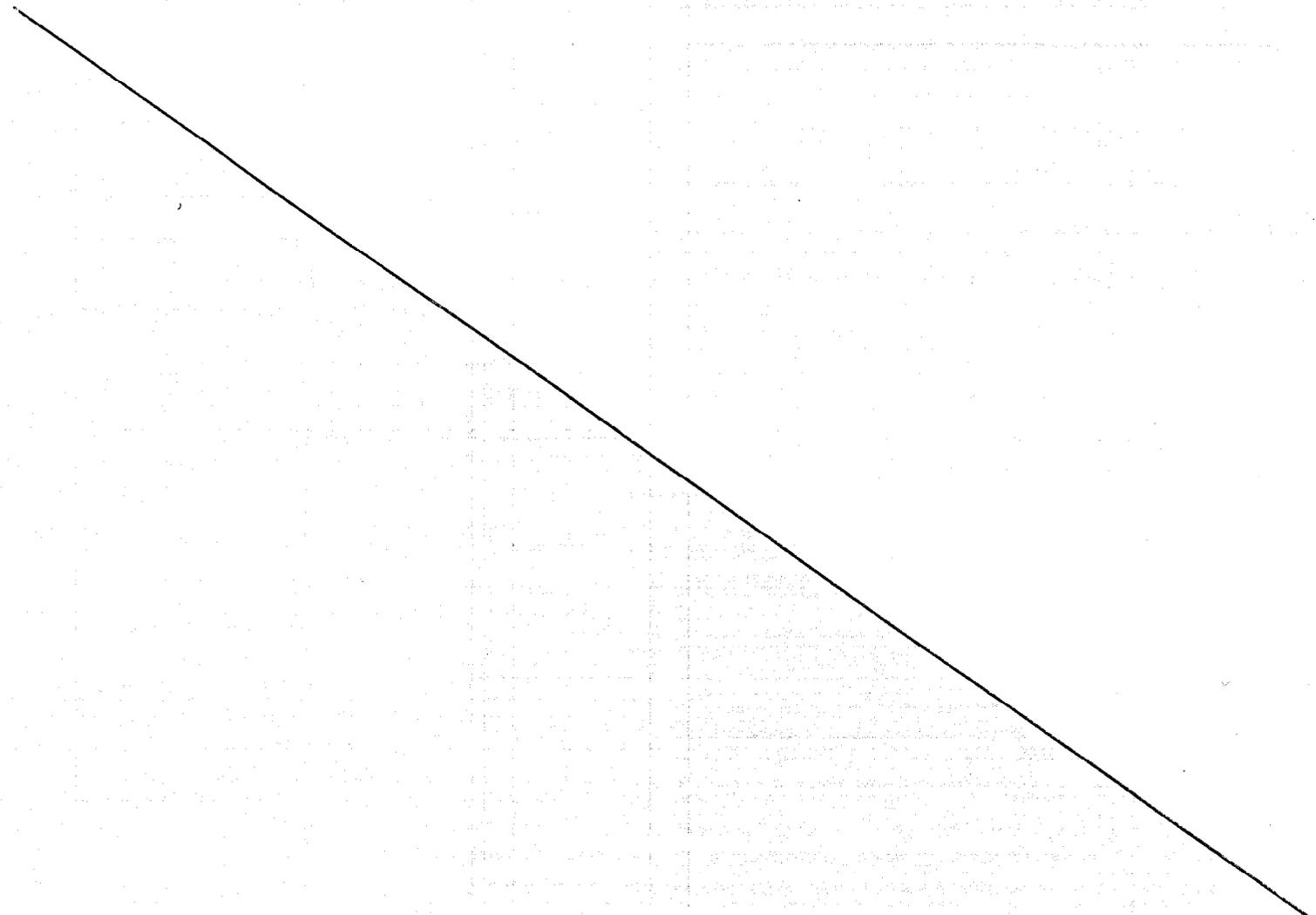
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical

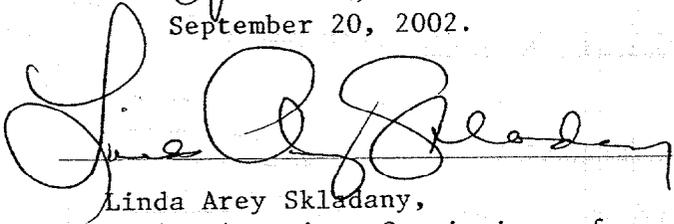
disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the October 10, 2002, Biological Response Modifiers Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Biological Response Modifiers Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).



Dated: Sept. 20, 2002
September 20, 2002.



Linda Arey Skladany,
Senior Associate Commissioner for
External Relations.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL.**

